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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,868	08/30/2005	Rejean Tremblay	701826-056380	1243

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,868	TREMBLAY ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/17/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 2/17/10 is acknowledged. Claims 1-6 and 12-14 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for a method of producing any polyunsaturated acids or any other product with *Chaetocerotaceae or Skeletonemaceae*. These families are not mentioned in the as filed specification.

Insertion of the limitation *Chaetocerotaceae or Skeletonemaceae* does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of *Chaetocerotaceae or Skeletonemaceae*. There is only one exemplified member of each of this families, i.e., *Chaetoceros gracilis* and *Skeletonema costatum* This is not sufficient support for the new genus *Chaetocerotaceae or Skeletonemaceae*. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of *Chaetocerotaceae or Skeletonemaceae* is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinnis *et al.* taken with Reitan *et al.* (Journal of Phycology, Volume 30, Issue 6 , Pages 972 - 979, 1994), newly cited, and Dempster and Taguchi *et al.*

The claims are directed to a method for producing polyunsaturated fatty acids from *Chaetocerotaceae or Skeletonemaceae*, wherein at least one growth-limiting factor is applied at the end of the exponential growth phase, causing growth arrest and production of polyunsaturated fatty acids.

McGinnis teaches a process of culturing diatomaceous algae for the production of polyunsaturated fatty acids wherein at least some of the diatoms where in exponential growth phase when growth limiting factors were applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., page 20, col. 2, paragraph 2.

Reitan *et al.* teaches a process of culturing diatomaceous algae for the production of polyunsaturated fatty acids wherein the algae are cultured in semi-continuous culture at a low growth rate under growth limitation. Growth arrest is achieved to some extent and the quantitative content of n-3 PUFAs is increased with increasing growth limitation. See, e.g., Table 2.

In addition, Dempster teaches a process of culturing diatomaceous algae wherein at least some of the diatoms are in exponential growth phase when growth limiting factors are applied, causing growth arrest and production of polyunsaturated fatty acids. See, e.g., pages 33-42.

The references differ from the claimed invention in that silicate deprivation is not disclosed and in that growth arrest does not necessarily occur at about 6 or 7 days.

However Taguchi *et al.* teach the influence of silicate deficiency on lipid synthesis by diatoms. Taguchi *et al.* studied the effects on *Chaetoceros gracilis, Hanstzschia* and *Cyclotella* strains and shows the favorable effects of lipid accumulation, including, of course, polyunsaturated fatty acids, after exponential growth and growth arrest. See, e.g., Fig 1.

Regarding the arrest of growth at about 6 or 7 days, there is no claim designated medium to obtain growth arrest at this time for any and all algae or even for *Chaetoceros gracilis* or *Skeletonema costatum.* It is apparent that the process in the specification in the Examples 1 and 2 requires semi-continuous culture, as in Reitan *et al.*, for example. It is noted that in Example 1 [0021], the **measurement** of fatty acids was effected 7 days after the stress, i.e., silicate deprivation, was initiated. There is no indication as to when exponential growth was attained or when the cultures reached growth arrest under semi-continuous culturing conditions. Similarly in Example 2, the **analysis** of the culture conditions was carried out 7 days after silicate deprivation was initiated.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of McGinnis *et al.* and Dempster by culturing diatomaceous algae under various growth-limiting conditions including silicate deprivation, as suggested by the teachings of Taguchi *et al.* for the expected benefit of maximizing the content of lipids in the diatomaceous algae cultures, including polyunsaturated fatty acids known to be useful in the pharmaceutical industries as well as being nutritionally essential to organisms such as oysters, fish and shrimp which are important nutrient sources for humans.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the alga in McGinnis was in stationary phase on day four. With all due respect, this is after the end of exponential phase, giving the claims its broadest reasonable interpretation. In claims 13 and 14, for example all that is required is monitoring growth and applying silicate deprivation "at the end of exponential phase" without an indication of the precise timing. On the other hand, in claim 12, the requirement is to apply a growth limiting factor "after 6 to 7 days". Therefore, this argument fails to persuade. Regarding the use of the term "culture", it is noted that in a cell culture it is statistically unlikely that absolutely all of the cells are in precisely the same growth stage simultaneously. This occurs if, and only if, the cells are precisely synchronized, which requires very specific culture conditions, tailored to the specific strain cultured. Clearly this is not the case in the invention as claimed, which includes broad families of organisms or entire species. Therefore it can reasonably be presumed that at least some cells are in exponential phase or at the end thereof.

From applicant's arguments it appears that applicant intends to culture specific cells under specific culturing conditions to achieve slow steady growth. However, there is nothing in the claims to specify or identify the strains cultured or the conditions required. The functional language used indicates desired results but fails to specify with particularity the means to achieve the results. The conditions that work for a certain strain of *Chaetoceros gracilis* have not been shown with objective evidence to produce similar results with any and all members of the families *Chaetocerotaceae or Skeletonemaceae* or even other members of the species.

Applicant asserts that McGinnis teaches against the invention because it mentions an increase in triglycerides while the "claimed invention provides, advantageously, a source of Omega-3-polyunsaturated acids." (Response, page 7). Applicant has not shown on this record that McGinnis fails to produce at least some Omega-3-polyunsaturated acids by the method used.

As noted previously, Reitan *et al.* demonstrate a clear correlation between nutrient limitation and an increase in quantitative PUFA production at least in *Chaetoceros* sp.. In order words, Reitan *et al.* clearly teach a process designed to enrich the amount of polyunsaturated fatty acids obtained in diatoms using growth-limitation techniques.

Regarding the Tremblay Declaration, the data in the declaration demonstrates that in *Chaetoceros gracilis* the production of polyunsaturated acids was increased after the "silicate stress" from 13.7% to 30.3%. It is noted in this regard that the percent of saturated acids plus monounsaturated acids is greater at 36.96% than that of polyunsaturated acids at 30.3%. Therefore, the silicate stress cannot be reasonably be concluded to result in "specifically producing polyunsaturated acids" from all possible diatomaceous algae or for "producing specifically polyunsaturated fatty acids" from all possible diatomaceous algae or even in *Chaetoceros gracilis* when applying "silicate stress" at days 6 or 7. Contrary to applicant's arguments there is no specificity in the methodology as claimed or in the methodology disclosed in the as-filed written disclosure.

It must be remembered that applicant has not shown on this record that the amount of polyunsaturated fatty acids in any *Chaetocerotaceae or Skeletonemaceae* is increased, or even in the particular species recited. In addition, it is apparent that the process steps of culturing diatomaceous algae in the references and as claimed are substantially the same. Therefore, one of ordinary skill in the art would have reasonably expected at the time the claimed invention was made that substantially the same results would be obtained, in the absence of evidence to the contrary.

Applicant's argument that the combined teachings of the references fail to show that silicate deprivation initiated at the end of exponential growth phase is critical for increase in omega-3-fatty acid production in *Chaetocerotaceae or Skeletonemaceae* is puzzling, since the present specification lacks such a teaching. See, also, the new matter rejection *supra.*

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651